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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/744,140

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Donald Michael Black

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06/15/2004

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

24

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,140

Applicant(s)

BLACK, DONALD MICHAEL

Examiner

William H. Matthews (Howie)

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 5-10 have been considered but moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1,5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the limitation “consisting essentially of administration of cholesterol lowering agent such as fibrates, atorvastatin, or carboxyalkyl ethers” lacks sufficient support in the specification. Applicant describes at page 10, line 12 the requirement for limited alcohol consumption, page 16 line 4 suggests administration of aspirin, and page 17 line 17 describes modifications to diet. Therefore modifications to diet, supplemental drugs, and reducing alcohol intake are included in applicant’s method. Applicant’s disclosure fails to disclose a method comprising solely the step of administering cholesterol-lowering agents. For purposes of examination “consisting essentially of” may be interpreted to include dietary modifications or additional drugs.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1,5,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seed et al. US PN 5,861,399 in view of Bocan WO 97/16184.

Seed et al. discloses in lines 47 of col. 2 through line 29 of col. 3. a method of treating patients having coronary artery disease comprising administering cholesterol lowering drug therapy to prevent the need for catheter based revascularization. Seed teaches in line 63 of col. 3 through line 4 of col. 4 the drug may be any cholesterol synthesis or transfer inhibitors such as simvastatin or lovastatin but lacks the express written disclosure of administering about 80 mg/day of atorvastatin. Bocan teaches in pages 2-5 that it is well known to use any of simvastatin, lovastatin, or atorvastatin in doses of about 80 mg/day in order to reduce blood lipids to a safe level.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Seed et al. by using 80 mg/day of Atorvastatin as taught by Bocan in order to reduce blood lipids to a safe level.

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6. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisgaier et al. US PN 5,648,387 in view of Seed et al. US PN 5,861,399.

Bisgaier discloses in lines 5-12 of col. 1, lines 26-35 of col. 2, and lines 35-62 of col. 6 a method of treating patients with coronary artery disease by administering effective amounts of cholesterol lowering drugs rather than other therapies. Bisgaier et al. discloses all elements of claims 7 and 8 but lacks the express disclosure of preventing or delaying a catheter based revascularization. Seed et al. teaches in lines 62 of col. 2 through line 20 of col. 3 that cholesterol lowering therapy may be used to prevent or delay the need for catheter based revascularization.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Bisgaier et al. by preventing a catheter based revascularization procedure as taught by Seed et al.

7. Claims 9,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seed et al. US PN 5,861,399 in view of Whitney et al. US PN 6,180,660 or Roth et al. WO 97/35576.

Seed et al. discloses in lines 47 of col. 2 through line 29 of col. 3. a method of treating patients having coronary artery disease comprising administering cholesterol lowering drug therapy to prevent the need for catheter based revascularization. Seed lacks the express written disclosure of the cholesterol lowering drug as a fibrate such as fenofibrate. Both Roth et al. (page 9) and Whitney et al. (cols 1-2) teach fenofibrate as an effective drug for lowering cholesterol levels.

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Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Seed et al. by using fenofibrate for the cholesterol lowering drug, as taught by each of Whitney and Roth et al., in order to lower cholesterol of the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM

WHM

June 9, 2004


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700